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\* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ W.P.(C) 5315/2020, CM APPL. 19189/2020(Direction)

MASTER ARNESH SHAW

..... Petitioner

Through: Mr. Rahul Malhotra and Ms. Anchal  
Tiwari, Advs.

Ms. Shyel Trehan, Amicus Curiae  
with Mr. Raghav Anand, Adv.

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Ripudaman Bhardwaj, CGSC for  
UII

Mr. Tanveer Obeori, Adv. for AIIMS

**CORAM:**

**HON'BLE MR. JUSTICE YASHWANT VARMA**

**ORDER**

**18.10.2022**

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1. Pursuant to the last order passed, the Union has filed an affidavit of compliance and appended thereto are the minutes of the 14<sup>th</sup> meeting of the Central Technical Committee for Rare Diseases [“CTCRD”] held on 02 September 2022. The CTCRD has in light of the order which was passed, proceeded to observe that as per the guidelines and procedures for extending financial assistance to patients suffering from rare diseases, it is of the opinion that the support up to a maximum of Rs.50 lakhs per patient is to be released for “treatment” of rare diseases. The CTCRD has expressed the view that the responsibility of conducting a clinical trial of a drug lies solely upon the drug developer until the efficiency and efficacy of that drug is duly proved. In view of the above, it has proceeded to record that “under trial”

drugs would not qualify as treatment and perhaps may not fall within the ambit of the support scheme as framed by the Union.

2. The Court, however, notes that it was this very aspect which was duly noticed in the order of 05 August 2022 where taking note of the stipulations contained in the Office Memorandum of 19 May 2022, it was noted that the expenses likely to be incurred in the course of administration of the trial drug may fall within the scope of financial aid for treatment. Undisputedly, all drugs which are being presently administered to children suffering from rare diseases are in one sense experimental therapies. This is evident from the stand expressed both on behalf of the Union as well as by the All India Institute of Medical Sciences [“AIIMS”] which had, while noticing the various drugs which are being presently imported, contended that there was a lack of definitive research material which may evidence the efficacy of the drugs being used for the purposes of treatment. Viewed in that light, the experimental drug which has been indigenously developed would also fall within the same category.

3. It was in the aforesaid backdrop that Court had requested the Union to consider whether the monetary support as envisaged under the Office Memorandum of 19 May 2022 could also be extended to the fifty-four (54) children who stand enrolled in the clinical trial.

4. The Court is thus of the considered view that the issue would warrant a more pragmatic view being taken bearing in mind the costs involved in the import of drugs which too are untried and untested.

5. The other issue which was raised and addressed by learned counsel representing CTCRD was that the release of Rs.50 lakhs per patient is linked to the treatment being undergone in a Centre of Excellence [“CoE”]. It is

submitted that not all the trial sites, which are nine in total, fall within the list of CoEs as drawn by the Union.

6. The Court however notes that out of the nine trial sites, at least the Indira Gandhi Institute of Child Health, Bangalore, AIIMS, Delhi and Post Graduate Institute of Medicine and Research, Chandigarh do fall within the category of Centres of Excellence. Consequently, the Union, while considering its decision with respect to the ambit of the Office Memorandum of 19 May 2022 afresh and whether its provisions would be applicable to clinical trials, may also consider the release of the grant as envisaged in respect of at least those patients who stand enrolled and form part of the clinical trial which is to be undertaken in the three trial sites noticed above. The CTCRD may also bear in mind the geographical constraints that may be faced by the patients enrolled in the clinical trial if the aforesaid restriction were to be strictly construed. However, the aforesaid directions are not liable to be construed as confining the CTCRD in any manner from considering the data which has been collated and placed before the DGCI in the trial phases which have been completed and independently evaluating whether the same would warrant further exploration.

7. The Court also takes on board the statement made by Mr. Oberoi, learned counsel appearing for AIIMS, who submits that the requisite funds for all the petitioners before this Court have been duly received by it and that the process of procurement of the necessary drugs and their import has already commenced. He assures the Court that expeditious steps shall consequently be taken to ensure that the procurement process is completed so that the treatment can commence thereafter.

8. The Court also takes note of the submissions independently addressed in respect of the petitioners in W.P.(C) 1491/2021 and W.P.(C) 1511/2021 who are stated to suffer from MPS II (Hunter Syndrome, Attenuated Type) disease. Insofar as the petitioner in W.P.(C) 1511/2021 is concerned, treatment is presently being administered based upon funds which were garnered by the parents of the child through a crowd funding exercise. Mr. Oberoi apprises the Court that the procurement process which has been initiated would also cover the treatment of the petitioners in W.P.(C) 1491/2021 and W.P.(C) 1511/2021.

9. In order to review progress and for the Union to revert back to the Court in light of the issues which stand flagged above, let this matter be called again on 29.11.2022 at 2:15 P.M along with CONT.CAS(C) 415/2022, CONT.CAS(C) 722/2022, W.P.(C) 11610/2017, W.P.(C) 2943/2020, W.P.(C) 10782/2020, W.P.(C) 322/2021, W.P.(C) 1491/2021, W.P.(C) 1511/2021, W.P.(C) 1611/2021, W.P.(C) 3662/2021, W.P.(C) 3682/2021, W.P.(C) 3689/2021, W.P.(C) 3706/2021, W.P.(C) 3707/2021, W.P.(C) 3729/2021, W.P.(C) 3737/2021, W.P.(C) 3859/2021, W.P.(C) 4045/2021, W.P.(C) 4067/2021, W.P.(C) 4259/2021, W.P.(C) 4304/2021, W.P.(C) 4551/2021, W.P.(C) 4812/2021, W.P.(C) 5394/2021, W.P.(C) 5395/2021, W.P.(C) 9684/2021, W.P.(C) 14317/2021 and W.P.(C) 1182/2022.

**YASHWANT VARMA, J.**

**OCTOBER 18, 2022**

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